



## **Transforming the Regulatory Environment to Accelerate Access to Treatments** **(TREAT ACT)**

The TREAT Act is commonsense bill that expedites development and access to safe and effective treatments for patients with serious or life-threatening diseases, including rare diseases. The bill ensures the best science and greater innovation in medical treatments with better access to expertise, while maintaining the FDA's high safety and effectiveness standards. The TREAT Act does this by:

1. Accelerating the review and approval processes for treatments that
  - a. Treat an unmet medical need,
  - b. Significantly advance the standard of care, or
  - c. Are highly targeted therapies for distinct sub-populations
2. Enhancing FDA access to external scientific and medical expertise. This is critical in areas where research is on the cutting edge.
  - a. It allows the FDA Commissioner to better utilize waivers when potential conflicts of interest are outweighed by the need to have input from leading medical and scientific experts.
3. Including patient advocates and disease research organizations in Advisory Committee reviews.
4. Ensuring that FDA provides drug sponsors with explanations of why their applications are rejected so that they might address concerns, improve the treatment and get the medications to patients.
5. Updating the FDA Mission Statement to reflect FDA's role in advancing medical innovation.
6. Creating a Management Review Board to enable the FDA to keep pace with the latest scientific advances.
7. Establishing a Chief Innovation Director to ensure rapid development, testing and review of new drugs and devices.
8. Establishing Chief Medical Policy Officers to address emerging medical and scientific policy issues at the Center for Drug Evaluation Research, Center for Biologics Evaluation Research, and the Center for Devices and Radiological Health.
9. Establishing a Clinical Informatics Coordinator to develop, implement and promote FDA's use of Health Information Technology in clinical research.

The TREAT Act does not authorize any government funding, and is not expected to receive any funding through the appropriations process. Instead, this bill transforms FDA's internal processes to ensure more consistency and clarity.